

Serial No. 09/674,819  
5774-01-MJA

### REMARKS

#### I. Status of the Application

This paper responds to a non-final Office action mailed on September 26, 2003. The original application was filed with claims 1-17. In response to a Restriction Requirement mailed August 29, 2001, Applicant amended claims 1 and 12 and added claims 18 and 19. In response to an Office action mailed February 6, 2002, which rejected all of the claims, Applicant amended claim 12, canceled claims 18 and 19, and added claims 20 and 21. A subsequent Final Office Action, which was mailed on November 1, 2002, maintained the rejection of claims 1-17, and rejected newly added claims 20 and 21. Applicant subsequently filed an RCE. In the submission that accompanied the RCE, Applicant amended claims 1-17, 20, and 21, and added claims 22-27. The present paper cancels claims 1-17 and 20-27 without prejudice or disclaimer and adds new claims 28-42. Accordingly, claims 28-42 are currently under consideration in this application.

By action taken here, Applicant in no way intends to surrender any range of equivalents beyond that needed to patentably distinguish the claimed invention as a whole over the prior art. Applicant expressly reserves all such equivalents that may fall in the range between Applicant's literal claim recitations and combinations taught or suggested by the prior art.

#### II. Petition for a Two-Month Extension of Time

This paper responds to a non-final Office action, which was mailed on September 26, 2003. The non-final Office action set a shortened statutory period for reply of three-months from the mailing date of the Office Action, making any response due on or before December 26, 2003. Applicant is filing this paper on February 21, 2004, which is within the second month following expiration of the shortened statutory period for reply. Applicant therefore petitions for a two-month extension of time and encloses the requisite fee under 35 CFR 1.17(a)(1).

(Amendment—page 5 of 8)

Serial No. 09/674,819  
5774-01-MJA

III. New Claims 28-42

Applicant has added new claims 28-42, which include independent claims 28 and 41. Independent claims 28 and 41 are similar to canceled claims 1 and 2, except that they list specific humectants and recite particular 4-amino-3-substituted butanoic acid derivatives, namely gabapentin and pregabalin. New dependent claims 29-40 and 42, are similar to canceled dependent claims 3-9, 11, 16, 17, 20, and 21. The specification, as filed, fully supports these new claims, and therefore Applicant submits that claims 28-42 introduce no new matter. See, for example, Application at page 5, lines 12-23; page 34, lines 2-9; and page 35, lines 1-10.

IV. Rejection of Claims 6, 13, 23, and 26 Under 35 U.S.C. § 112

The Office action rejected claims 6, 13, 23, and 26 under 35 U.S.C. § 112, second paragraph, alleging that the term "lower," which immediately precedes "aliphatic acid ester of glycerol," renders the claims indefinite. As noted above, Applicant has canceled claims 6, 13, 23, and 26, thereby obviating the rejection as to those claims. None of the new claims use the term "lower." Therefore, Applicant respectfully requests withdrawal of the rejection.

V. Rejection of Claims Under 35 U.S.C. §§ 102/103

The Office action rejected claims 1, 10-12, 14, 22, and 25 under 35 U.S.C. §§ 102/103 as allegedly being anticipated or rendered obvious by US 6,054,482 in view of US 5,302,373, Telev (abstract), US 5,618,342 and/or BE 645,388. The Office action also rejected claims 1, 2, 7-14, 22, and 25 as allegedly being anticipated or rendered obvious by EP 458,751. The Office action rejected claims 1, 7-17, and 20-21 as allegedly being anticipated or rendered obvious by US 4,126,684, and also rejected claims 1-7, 10-15, and 20-27 as allegedly being anticipated or rendered obvious by US 5,025,035. Applicant respectfully traverses the rejections.

As noted above, Applicant has added new claims 28-42, which claim stabilized solid compositions and methods for stabilizing such compositions. All of the claims list specific humectants and recite particular 4-amino-3-substituted-butanoic acid derivatives,

(Amendment—page 6 of 8)

Serial No. 09/674,819  
5774-01-MJA

namely gabapentin and pregabalin. None of the references applied in the latest Office expressly disclose solid compositions or methods for stabilizing such compositions, which comprise gabapentin or pregabalin or both gabapentin and pregabalin and the specified humectants. Therefore, Applicant submits that none of the references of record anticipate claims 28-42.

Furthermore, whether viewed alone or in combination, none of the references render claims 28-42 obvious. As described on pages 3 and 4 of the specification, pharmaceutical preparations containing gabapentin or similar 4-amino-3-substituted-butanoic acid derivatives are difficult to prepare because the active ingredient may undergo lactamization. As demonstrated in the examples, Applicant has discovered that the addition of certain humectants to solid compositions containing gabapentin or pregabalin will prevent lactam formation, i.e., will stabilize the solid composition.

This result is completely unexpected. None of the references even hint that humectants will stabilize formulations containing gabapentin, pregabalin, or similar 4-amino-3-substituted-butanoic acid derivatives. The references list a few humectants among many excipients. These excipients belong to many different classes and serve many different purposes in pharmaceutical formulations. The references provide little guidance as to which excipients will or will not stabilize gabapentin and similar 4-amino-3-substituted-butanoic acid derivatives. Thus, at most, the references represent an obvious to try rationale, which does not render the claims obvious. Therefore, Applicant respectfully submits withdrawal of the rejection and allowance of the pending claims.

#### VI. Conclusion

In view of the foregoing, Applicant respectfully submits that all pending claims are patentable over the references of record. If the Examiner has any questions, Applicant requests that the Examiner telephone the undersigned.

Applicant believes that any fees associated with the filing of the present amendment have been identified in a transmittal that accompanies this paper. However,

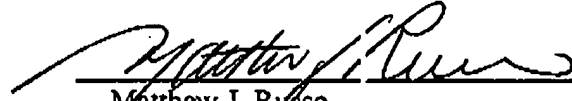
(Amendment—page 7 of 8)

Serial No. 09/674,819  
5774-01-MJA

if any fees are required in connection with the filing of this paper, and such fees have not been identified in the accompanying transmittal, please charge deposit account number 23-0455.

Respectfully submitted,

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(Amendment—page 8 of 8)